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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,630	04/10/2001	Koral Embil	888-50	6577

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EXAMINER

JONES, DWAYNE C

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 03/27/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/762,630

Applicant(s)

EMBIL ET AL.

Examiner

Dwayne C Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on the 28 JAN 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Status of Claims

1. Claims 19-38 are pending.
2. Claims 19-38 are rejected.

Priority

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 18-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jain et al. of EP 812,587 A1 possessing a publication date of December 17, 1997. Jain et al. teach of a non-staining composition of nimesulide, which contains monoglycerides, such as glycerol monooleate, in an amount ranging from 0.5 % to 12 % by weight, (see abstract and page 4, lines 4-13 and 42-43 and page 5, lines 14 and 15). Moreover, Jain et al. teach that it is well known in the art that nimesulide possesses both anti-inflammatory and analgesic properties, (see page 2, lines 5-20). Also, Jain et al. teach of including the presence of hydroxypropyl cellulose as a gelling agent, (see page 4, lines 44-52). Jain et al. also teach of methods of making compositions that contain nimesulide, (see page 4, lines 1-13). In the steps, Jain et al. teach of stirring and mixing the nimesulide in order to dissolve the nimesulide. Jain et al. also teach of combining the surfactants, in particular glycerol monooleate, along with the nimesulide mixture by obvious laboratory synthesis reaction techniques, such as stirring, mixing , changing parameters such as pH, pressure or temperature. Furthermore, Jain et al.

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disclose that these therapeutic compositions may be used as a gel, emulsion, cream, solution, ointment or aerosol, (see page 5, lines 16-29). Generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955), see also *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). It would have been obvious to one having ordinary skill in the art to optimize the range of the glyceryl monoolein in order to improve the surfactant properties of the sparingly soluble nimesulide. In addition, it is within the purview of the skilled artisan to utilize these topical compositions that contain nimesulide for ailments that are alleviated or treated with a compound that has anti-inflammatory and analgesic properties. In addition, the skilled artisan would have been motivated to formulate compositions of nimesulide with the glycerin monooleate by synthesis techniques that are known in the art, such as stirring, mixing, changing parameters such as pH, pressure or temperature. Accordingly, it would have been obvious to the skilled artisan to perform well known synthesis techniques in order to make formulations that contain nimesulide along with the glycerin monooleate

8. Claims 18-25 and 30-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kruse et al. of U.S. Patent No. 5,744,458. Kruse et al. teach of a topical composition, which contains nimesulide, (see column 121, line 48) and glyceryl mono-fatty acid esters, (see column 115, lines 50-64). In addition, Kruse et al. teach

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that the glyceryl mono-fatty acid esters are present in the composition in from 1% to 50 %, (see column 114, lines 34-36 and 39-42). Although the prior art reference of Kruse et al. do not specifically recite the glyceryl monoolein, this obviously falls within the meaning a glycerol mono-fatty acid, and thus is in the purview of the skilled artisan. For these reasons, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any fatty acid, including oleic acid, to be usable along with an active agent such as nimesulide. In addition, it is within the purview of the skilled artisan to utilize these topical compositions that contain nimesulide for ailments that are alleviated or treated with a compound that has anti-inflammatory and analgesic properties due to the fact that it is known in the art that nimesulide possesses anti-inflammatory and analgesic properties.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

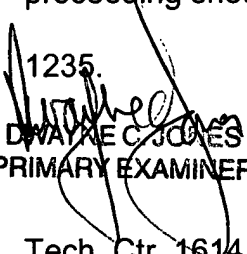
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1235.


DWAYNE C. JONES
PRIMARY EXAMINER

Tech. Ctr. 1614
March 21, 2003